

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

BURTON L. APPLETON,	:		
	:		
Plaintiff,	:	Civil Action No.:	02-1043 (RMU)
	:		
v.	:	Document Nos.:	10, 13, 18, 23, 26, 28
	:		
FOOD AND DRUG ADMINISTRATION	:		
and DEPARTMENT OF HEALTH AND	:		
HUMAN SERVICES,	:		
	:		
Defendants.	:		

MEMORANDUM OPINION

**GRANTING IN PART THE DEFENDANTS' MOTION FOR AN *OPEN AMERICA* STAY;
DENYING WITHOUT PREJUDICE THE MOTIONS TO INTERVENE**

I. INTRODUCTION

Plaintiff Burton Appleton, a former Food and Drug Administration ("FDA") chemist, brings this action *pro se* to compel FDA to reply fully to his Freedom of Information Act ("FOIA") request for records regarding the drug levothyroxine sodium. Defendants FDA and the Department of Health and Human Services ("HHS") have submitted a partial answer and a motion for a stay of proceedings pending the completion of their search and production of documents pursuant to the FOIA request (known as an *Open America* stay). In addition, Jerome Stevens Pharmaceuticals, Inc., Jones Pharma, Inc., Abbott Laboratories, Lloyd Inc., and Vintage Pharmaceuticals, Inc. have filed motions to intervene. For the reasons that follow, the court grants in part and holds in abeyance in part the defendants' motion for an *Open America* stay, and denies without prejudice the motions to intervene.

II. BACKGROUND

A. Factual Background

In September 2001, the plaintiff submitted a FOIA request to FDA, requesting "any and all records concerning communications 1) between [FDA] and the United States Pharmacopeia ["USP"] . . . and 2) within the FDA on the subject of the drug levothyroxine sodium." Compl. Ex. 1. Specifically, he asked for communications – including letters, faxes, e-mails, memoranda, and directives – from August 14, 1997 to the present regarding orally administered and injectable dosage forms of the drug. *Id.*

In response to the plaintiff's request, FDA responded four times.¹ On October 4, 2001, FDA responded with a brief letter acknowledging receipt of the plaintiff's request, assigning it a file number, and stating that the agency would respond "as soon as possible." Defs.' Mot. for Stay Ex. 1B. On November 1, 2001, FDA sent a second, more substantive response noting that information on a certain relevant new drug application (Unithroid) was available on FDA's website, that information on another relevant new drug application (Levoxyl) required redaction before release, and that a search was underway for the FDA/USP communications. *Id.* Ex. 2A. On December 7, 2001, FDA sent the plaintiff redacted information on the Levoxyl application. *Id.* Ex. 2B. Finally, on January 2, 2002, FDA forwarded material on FOIA law and regulations to the plaintiff.² Compl. Ex. 2.

On January 25, 2002, the plaintiff wrote to FDA to raise concerns regarding the agency's

¹ Between November 2001 and March 2002, the plaintiff also initiated several telephone calls in which he and various FDA officials discussed the status of his request. Defs.' Mot. for Stay Ex. 2 at 12 n.3; Pl.'s Opp'n at 31.

² The January 2, 2002 correspondence may have been in response to a separate December 14, 2001 request by the plaintiff to FDA for FOIA information. Pl.'s Opp'n Ex. 11.

responses, and to amend his original request. *Id.* Specifically, the plaintiff highlighted what he believed to be various insufficiencies in the FDA responses, such as inaccurate paraphrasing of his request, missing documents, and unnecessary redactions. *Id.* He also amended his request to enlarge the time frame from August 14, 1997 to "the first time that the FDA began to look into the regulation of the drug." *Id.* At the same time, he clarified the parameters of his request (stating, for example, that his request was intended to focus primarily on chemistry information, with biopharmaceutical information requested only insofar as it invoked analytical chemistry methodology not elsewhere disclosed). *Id.*

After receiving no response from FDA, on March 26, 2002 the plaintiff faxed a letter to HHS to appeal FDA's denial of his FOIA request. *Id.* Ex. 3. On March 28, 2002, at the direction of HHS staff, the plaintiff redirected his fax to a different number. *Id.* Ex. 4. On March 28 and 29, 2002, the plaintiff received acknowledgment of his appeal. *Id.* On May 8, 2002, after receiving no substantive response to his March letter, the plaintiff again wrote to HHS to stress what he believed were FDA's "repeated failures" to abide by FOIA and to ask for information in order to avoid "go[ing] to federal district court prematurely." *Id.*

B. Procedural History

On May 29, 2002, the plaintiff filed a complaint with this court. On July 1, 2002, the defendants filed a partial answer accompanied by a motion requesting an *Open America* stay of proceedings through March 15, 2004. Subsequently, five pharmaceutical manufacturers – Jerome Stevens Pharmaceuticals, Inc., Jones Pharma, Inc., Abbott Laboratories, Lloyd Inc., and Vintage Pharmaceuticals, Inc. – filed motions to intervene.

III. ANALYSIS

A. The Court Grants in Part the Motion for an *Open America* Stay of Proceedings and Denies Without Prejudice the Motions to Intervene

1. Legal Standard for a Stay of Proceedings Pursuant to 5 U.S.C. § 522(a)(6)(C)

Pursuant to FOIA, an agency that has received a request for records must respond to that request within twenty working days of the date of receipt of the request. 5 U.S.C. § 552(a)(6)(A). To prevent this deadline from becoming rigid and unworkable, however, Congress inserted a special "safety valve." *Open Am. v. Watergate Special Prosecution Force*, 547 F.2d 605, 610 (D.C. Cir. 1976). Specifically, Congress provided that "[i]f the Government can show exceptional circumstances exist and that the agency is exercising due diligence in responding to the request, the court may retain jurisdiction and allow the agency additional time to complete its review of the records." 5 U.S.C. § 522(a)(6)(C)(i).

As defined by this circuit in *Open America*, "exceptional circumstances" exist when an agency "is deluged with a volume of requests for information vastly in excess of that anticipated by Congress, when the existing resources are inadequate to deal with the volume of such requests within the time limits of subsection (6)(A), and when the agency can show that it 'is exercising due diligence' in processing the requests." *Open Am.*, 547 F.2d at 616. In the Electronic Freedom of Information Act Amendments of 1996, however, Congress made clear that "exceptional circumstances" do not include delays stemming "from a predictable agency workload of requests . . . unless the agency demonstrates reasonable progress in reducing its backlog of pending requests."³ 5 U.S.C. § 522(a)(6)(C)(ii).

³ "*Open America* represents the law of the Circuit and has been applied to FOIA cases since the 1996 amendments." *Emerson v. Cent. Intelligence Agency*, 1999 U.S. Dist. LEXIS 19511, at *4 (D.D.C. Dec. 15, 1999). *But see Donham v. Dep't of Energy*, 192 F. Supp. 2d 877, 880 (S.D. Ill. 2002) (suggesting indirectly that the 1996 amendments superseded the *Open America* standard).

Courts in this circuit have interpreted this "exceptional circumstances" provision as excusing any delays encountered in responding to a request as long as the agencies are making good-faith efforts and exercising due diligence in processing requests on a first-in, first-out basis. *Open Am.*, 547 F.2d at 616; *Ohaegbu v. Fed. Bureau of Investigation*, 936 F. Supp. 7, 8 (D.D.C. 1996) (citing *Kuffel v. Bureau of Prisons*, 882 F. Supp. 1116, 1127 (D.D.C. 1995)).

2. Good-faith Efforts and Due Diligence

In this case, the defendants argue that an *Open America* stay is warranted because FDA has exercised due diligence both in processing the plaintiff's FOIA request and in reducing its backlog of FOIA requests on a first-in, first-out basis. Defs.' Mot. for Stay at 9-13. First, with regard to the plaintiff's request, the defendants state that upon receiving the request, FDA Division of Freedom of Information ("DFOI") staff logged it, forwarded it to FDA's Division of Information Disclosure Policy ("DIDP"), and sent the October 4, 2001 letter of acknowledgment to the plaintiff. *Id.* at 2-3, Ex. 1 (Dorsey Decl.) at 2-3. Subsequently, DIDP staff provided the plaintiff with readily available documents via the November 1 and December 7, 2001 letters, and placed the remainder of his request on FDA's "complex" track, which operates on a first-in, first-out basis. *Id.* at 9-10, Ex. 2 (Masciale Decl.) at 11-13. Second, the defendants argue that FDA has made significant efforts to reduce its FOIA backlog. *Id.* Ex. 1 (Dorsey Decl.) at 4. They note that although FDA had a backlog of 16,704 requests in fiscal year 1998, the agency reduced this backlog to 14,193 by the end of fiscal year 2001. *Id.* To aid its backlog reduction efforts, in 2001 the FDA upgraded DIDP – which receives a quarter of all FDA FOIA requests – to a fully independent division, with additional personnel and resources. *Id.* at 11-13. The defendants note that DIDP also recently implemented new electronic filing and redaction systems. *Id.* at 12.

In response, the plaintiff acknowledges the *Open America* standard but urges the court to focus on Judge Leventhal's concern that the majority's view "permit[s] open-ended approval of agency failure to meet the Act's specific time limits." Pl.'s Opp'n at 2-5 (citing *Open Am.*, 547 F.2d at 618 (Leventhal, J., concurring)). Moreover, the plaintiff vigorously disputes the defendants' contentions of due diligence. Stating that the defendants have demonstrated a cavalier disregard for his request, he argues that the requested documents are easily located and obtained, and should require no consultation with other offices or agencies. Pl.'s Opp'n at 12, 14, 21, 34-36. The plaintiff also disputes any inference of agency due diligence based on the communications between the parties, stating that he initiated all calls regarding his request and that some of the dates of the defendants' correspondence are questionable. *Id.* at 15-16, 31, 33. As for the defendants' diligence in reducing its FOIA backlog, the plaintiff contends that the backlog is "nothing special or acute or exceptional," and points out that viewed as a percentage of the number of overall requests, the backlog between fiscal years 1998 and 2001 shows an increase rather than a decrease. *Id.* at 41-43. Finally, the plaintiff, who is approaching 81 years of age, opposes a stay on the grounds that "[t]ime is no friend of his." Pl.'s Opp'n at 10-11.

After reviewing the parties' submissions, the court concludes that according to the law of this circuit, the defendants have demonstrated good-faith efforts and due diligence in processing the plaintiff's request on a first-in, first-out basis. *Open Am.*, 547 F.2d at 616; *Ohaegbu*, 936 F. Supp. at 8. The declarations of the DFOI and DIDP directors attest to a good-faith, diligent effort to process the plaintiff's request pursuant to FDA's first-in, first-out complex track. Defs.' Mot. for Stay Ex. 1 at 2-3, Ex. 2 at 11-17. In addition, FDA has shown reasonable progress in reducing its backlog between

fiscal year 1998 and fiscal year 2001.⁴ *Id.* Ex. 1 at 4; Defs.' Reply at 8-9. Accordingly, the court grants in part the defendants' motion for an *Open America* stay.⁵

3. The Scope of the Plaintiff's Request

Because it is clear that there is some confusion between the parties as to the scope of the plaintiff's request, however, the court will hold in abeyance that part of the defendants' motion that requests a March 15, 2004 deadline. The defendants, who believe that the plaintiff's January 25, 2002 letter greatly expanded the scope of his request, assert that the request is complex and will require review of "a universe of documents [dating] back to the 1950s." Defs.' Mot. for Stay at 4, Ex. 2 at 5, 13, 16. They note that the plaintiff's opposition to their motion suggests that they can place certain limitations on his search, but note that the plaintiff has not formally narrowed his request in any way. Defs.' Mot. for Stay Ex. 2; Defs.' Reply at 11. The plaintiff strenuously disputes that his request is complex. Pl.'s Opp'n at 28. He explains that he is seeking not "the clutter of documents" implied by the defendants, but chemistry matters in certain drug applications and drug master files, laboratory work, and administrative documents. *Id.* at 28, 31-32. The plaintiff suggests that the DIDP director "confine her search initially to the Metabolic and Endocrine Drug unit [and] have the files of the

⁴ As noted, the plaintiff points out that FDA's FOIA backlog decreased by increasingly smaller margins from fiscal year 1998 to fiscal year 2001, and actually increased by 971 requests in fiscal year 2000. Pl.'s Opp'n at 19-20. "Reasonable progress," however, does not require that annual backlog reductions be uniform.

⁵ Although the plaintiff's age understandably factors into his views on the pending motion, the age of the requesting party is not a factor that courts are to consider in evaluating a motion for an *Open America* stay. 5 U.S.C. § 522(a)(6)(C)(i); *Open Am.*, 547 F.2d at 616. Nor does FOIA provide for expedited consideration of FOIA requests based on age. 5 U.S.C. §§ 552(a)(6)(E) (allowing expedited consideration in cases of "compelling need" where failure to obtain the requested records "could reasonably be expected to pose an imminent threat to the life or physical safety of an individual").

The defendant's age, however, is another consideration favoring clarification of the scope of request. *See infra*.

Compendial Operations Staff (COS) scoured [and] forget all those other places mentioned in footnote 5 of her declaration." *Id.* at 34-35.

Similar confusion permeates the submissions relating to the motions to intervene. For example, Jerome Stevens⁶ states that the content at issue is "[1] Unithroid's quan[t]itative formula, [2] the order in which Unithroid's ingredients are added together, [3] the steps that the additions go through in the formation of Unithroid's tablets, and [4] the processing of the active ingredient." Mot. to Intervene (Jerome) at 1 n.2. In response, the plaintiff contends that he "has made it perfectly clear that he is not interested in" the second and third items, "is interested in item 1 insofar as it pertains to a listing of the inactive ingredients of the dosage with respect to the concept of the public's right to know what is in a medication he is ingesting," and "would, at a minimum, have to have an explanation . . . for JSP's reasons to keep [items 1 and 4] secret." Pl.'s Opp'n (Jerome) at 10, 12. Likewise, Abbott avers that the plaintiff seeks "records containing Abbott's trade secret and confidential commercial information, including detailed scientific and medical data about the methods Abbott uses to make, prepare, and process Synthroid." Mot. to Intervene (Abbott) at 2. The plaintiff counters that he "is not interested in Abbott's confidential commercial or financial data [or] in medical or pharmacological data except insofar as either is or may be related to the state of purity of the active ingredient" Pl.'s Opp'n (Abbott) at 3.

Clearly, the scope of the plaintiff's request is critical. Not only does it drive the deadline by which FDA should complete its production, but it directly affects the ability and inclination of others to

⁶ Prior to the filing of its motion to intervene, counsel for Jerome Stevens and the plaintiff exchanged calls and letters in an attempt to clarify the scope of the plaintiff's request with an eye to avoiding intervention, but this attempt seems to have broken down after a dispute arose over what had or had not been signed and/or agreed to. Mot. to Intervene (Jerome Stevens) at 1 n.1; Pl.'s Opp'n (Jerome Stevens) at 2-8; Reply (Jerome Stevens) at 4 n.10.

intervene. Whatever the source, the uncertainty surrounding the request has resulted in unnecessary delay and expenditure of resources by the parties, the movants, and the court.

To prevent further squandering of time or resources, the court directs the parties to confer in an effort to clarify the plaintiff's request. After conferring, the parties shall submit a joint status report to the court outlining the results of their conference and proposing a deadline for the completion of the defendants' production of documents.⁷ In the interim, the court will hold in abeyance that part of the defendants' motion relating to the March 15, 2004 deadline.

IV. CONCLUSION

For the foregoing reasons, the court grants in part and holds in abeyance in part the defendants' motion for an *Open America* stay. The court also dismisses the pending motions to intervene, but does so without prejudice to ensure that the movants may refile their motions after the submission of the joint status report if intervention is still necessary. An order consistent with this Memorandum Opinion is separately and contemporaneously issued this 27th day of February, 2003.

Ricardo M. Urbina
United States District Judge

⁷ In effect, the parties should re-engage in the meet-and-confer session required prior to the filing of a nondispositive motion. Local Civil Rule 7.1(m). The defendants did inform the court that they contacted the plaintiff to determine his position on their motion. Defs.' Mot. for Stay at 2. The purpose of Rule 7.1(m) is not to "simply determine whether the motion will be opposed," however, but "to force litigants to attempt to resolve, or [at] least narrow, the disputed issues to prevent the unnecessary waste of time and effort on any given motion." *Alexander v. Fed. Bureau of Investigation*, 186 F.R.D. 187, 199 (D.D.C. 1999).

By ensuring that the request does not "become so complicated that no man alive knows what it means," the parties can avoid the "*Jarndyce v. Jarndyce* proceeding" of which the plaintiff so colorfully warns. CHARLES DICKENS, *BLEAK HOUSE* ch. 1 (Norman Page ed., Penguin Books 1971) (1853); Pl.'s Opp'n at 10.

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